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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/823,038	03/28/2001	Lorna Strachan	11000.1037c3	1046

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EXAMINER

LI, RUIXIANG

ART UNIT PAPER NUMBER

1646

DATE MAILED: 09/10/2002

16

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/823,038

Applicant(s)

STRACHAN

Examiner

Ruixiang Li

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 01 July 2002.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 13-21, 23, 25 and 29-38 is/are pending in the application.
- 4a) Of the above claim(s) 13-21 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 23, 25 and 29-38 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 28 March 2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 15.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

DETAILED ACTION

I. Status of Application, Amendments, and/or Claims

Applicants' Response filed on July 1, 2002 in Paper No. 14 has been entered in full. Claims 24 and 26-28 have been canceled. Claims 23 and 25 have been amended. Claims 29-38 have been added. Claims 13-21, 23, 25, and 29-38 are pending and Claims 23, 25, and 29-38 are currently under consideration.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office Action.

II. Information Disclosure Statement

All the references that the Examiner initialed in PTO-1449 form submitted in paper No. 4 on 07/12/2001 were considered in the previous office action. All the references included in the newly submitted PTO-1449 in paper No. 15 have now been considered.

III. Withdrawn Objections and/or Rejections

The objection to the disclosure as set forth in the previous Office Action (Paper No. 13, May 17, 2002) stands. It is noted that the embedded hyperlink has been deleted from the specification. However, the error in reference to a parent application 09/383,586 (filed on August 26, 1999), which has been issued as U. S. Patent No. 6,242,419, has not been corrected. Applicant is required to correct the error.

The rejection of Claims 23-28 under 35 U.S.C. §112, second paragraph, as set forth at pages 5-6 of the previous Office Action (Paper No. 13, May 17, 2002), has been

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withdrawn in view of applicants' amendment of Claims 23 and 25 and cancellation of Claims 26-28.

The objection of Claims 23-28, as set forth at page 6 of the previous Office Action (Paper No. 13, May 17, 2002), has been withdrawn in view of applicants' amendment of Claims 23 and 25 and cancellation of Claims 26-28.

IV. Claim Rejections—35 USC § 112, 1st paragraph

(i) The rejection of Claims 25-28 under 35 U.S.C. §112, first paragraph, as set forth at pages 3-5 of the previous Office Action (Paper No. 13, May 17, 2002), is replaced by the following rejection.

(ii) The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

(iii) Claims 23, 25, and 29-38 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected to use the invention.

The factors considered when determining whether a disclosure satisfies enablement requirement include: (i) the quantity of experimentation necessary; (ii) the amount of direction or guidance presented; (iii) the existence of working examples; (iv) the nature of the invention; (v) the state of the prior art; (vi) the relative skill of those in the art; (vii) the predictability or unpredictability of the art; and (viii) the breadth of the claims. *Ex Parte Forman*, 230 USPQ 546 (Bd Pat. App. & Int. 1986); *In re Wands*, 858 F. 2d 731, 8 USPQ 2d 1400 (Fed. Cir. 1988).

Claims 23, 25, and 29-38 are drawn to a method for modulating an immune response in a patient comprising administering to the patient a composition comprising an isolated polypeptide comprising SEQ ID NO:33. The instant disclosure discloses enhancement of proliferation of adherent peripheral blood mononuclear cells (Example 8) and activation of natural killer cells (Example 9) by murine FGFR5 β (SEQ ID NO:31) and FGFR5 γ (SEQ ID NO:32). However, the instant disclosure is silent about the mechanism of the action of these murine FGF receptors. It is unclear why and how addition of a FGF receptor to the cultured adherent peripheral blood mononuclear cells enhances its proliferation or to the cultured natural killer cells causes its activation. There is no indication in the art that such a FGF receptor like the one instantly claimed would enhance immune response at the time when the instant application was filed. Furthermore, while SEQ ID NO:33 shares 77.1% and 57.8% sequence homology with FGFR5 β (SEQ ID NO:31) and FGFR5 γ (SEQ ID NO:32), there is no evidence that the polypeptide of SEQ ID NO:33 would act in the same manner as do SEQ ID NOS:31 and 32, because the mechanism of action of FGFR5 β (SEQ ID NO:31) and FGFR5 γ (SEQ ID NO:32) are unclear. The instant disclosure fails to provide sufficient guidance, working examples on how to use the polypeptide of SEQ ID NO:33 to enhance an immune response.

Even if the effect of FGFR5 β (SEQ ID NO:31) and FGFR5 γ (SEQ ID NO:32) on the immune cells are a true nature of these polypeptides, the instantly claimed polypeptide may not possess the properties of FGFR5 β (SEQ ID NO:31) or FGFR5 γ (SEQ ID NO:32) because the instantly claimed polypeptide is 204 amino acid

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residues shorter than FGFR5 β (SEQ ID NO:31) or 117 amino acid residues shorter than FGFR5 γ (SEQ ID NO:32) and there is no description about which region of the polypeptide is critical to the immune regulatory effect.

It should also be noted that a method for modulating an immune response should be revised as a method for enhancing an immune response because a polypeptide with a define structure can only have a specific effect, and cannot function in both ways: up-regulating and down-regulating an immune response.

In view of these factors, it would require undue experimentation for one skilled in the art to use the claimed invention embraced by the instant claims.

V. Conclusion

No claims are allowed.

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ruixiang Li whose telephone number is (703) 306-0282. The examiner can normally be reached on Monday-Friday, 8:30 am-5:00 pm.

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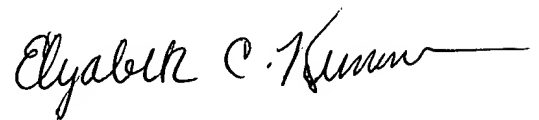
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler, can be reached on (703) 308-6564. The fax phone number for this Group is (703) 305-3014 or (703) 308-4242.

Communications via Internet e-mail regarding this application, other than those under 35 U.S.C. 132 or which otherwise require a signature, may be used by the applicant and should be addressed to [yvonne.eyler@uspto.gov].

All Internet e-mail communications will be made of record in the application file. PTO employees do not engage in Internet communications where there exists a possibility that sensitive information could be identified or exchanged unless the record includes a properly signed express waiver of the confidentiality requirements of 35 U.S.C. 122. This is more clearly set forth in the Interim Internet Usage Policy published in the Official Gazette of the Patent and Trademark on February 25, 1997 at 1195 OG 89.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Ruixiang Li
Examiner
September 4, 2002



ELIZABETH KEMMERER
PRIMARY EXAMINER